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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/665,240
Filing Date: September 19, 2003
Appellant(s): EKSTROM, TOMMY

Janis K. Fraser
Reg. No. 34,819
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 2, 2011 appealing from the Office action mailed August 20, 2010.

The Examiner would like to note to the Board and all that are concerned of a clerical error on page 10, line 7 and 11, line 12 of the Final Office Action filed August 20, 2010. Please insert “not” between does and teach such that the sentence reads "carling et al. does not teach...".

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board’s decision in the pending appeal:

The Board of Patent Appeals and Interferences issued a decision in Appeal 2007-154 in a related case, U.S. Serial No. 09/367,950, on August 28, 2007. The present application is a continuation of that related case. The examiner is not aware of any other prior or pending related appeals, judicial proceedings, or interferences.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 13-29, 34, 36, 42-68 are rejected and under appeal. Claims 1-12, 30-33, 35, 37-41, 51, 56, 67 and 68 are canceled.

(4) Status of Amendments After Final

The amendments to the claims to cancel claims 51, 56, 67 and 68 are entered. The examiner has no further comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

Due to the abandonment of the U.S. Application 09/367,950 the provisional double patenting rejection is WITHDRAWN.

All 35 U.S.C. 103(a) rejection of cancelled claims 51, 56, 67 and 68 are WITHDRAWN.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,795,564	Aberg et al.	08-1998
5,983,956	Trofast	11-1999
WO 9311773 A1	Carling	06-1993

Ryrfeldt et al. "Pulmonary disposition of the potent glucocorticoid budesonide, evaluated in an isolated perfused rat lung model", Biochemical Pharmacology, 1989, vol. 38, no. 1, pp.17-22.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 13-15, 17, 18, and 20-29, 34, 36, 42-50 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling.

Carling et al. teaches suitable daily asthmatic dose of formoterol (as fumarate dihydrate; see page 8, line 6; addresses applicant's claims 13, 15, 17-18, 26-27, 36, 42 and 49-55) and/or a physiologically acceptable salt and/or solvent thereof and budesonide twice a day (i.e. on demand; see page 4, lines 24-28; page 6, lines 5-30, addresses applicant's claims 13, 35, 36, 42 and 49-50). The combination of the two drugs have greater efficiency and duration of bronchodilator action, and rapid onset action, which provides rescue medicine, adequate dosing for treating asthma (see page 4, lines 4-21; addresses applicant's claims 13, 36, 42 and 49-50). This new feature is of utmost importance in order to establish a higher compliance for patients and it provides a rescue medicine thereby avoiding the necessity for the patient of carrying two different inhalers (see page 4, lines 4-10; addresses claim 48). Formoterol is administered in a suitable daily dose in a range of 6 to 100 μg with a daily dose of budesonide in a range of 50 to 4800 μg (see page 6, lines 24 and 26; addresses applicant's claims 17, 18, 20, 21, and 27-29). The dosages strongly depends on the patient (age, weight etc.), severity of disease (mild, moderate, severe asthma etc..); see page 6, lines 27-29. The ratio of formoterol to budesonide is in the range of 1:4 to 1:70, which can be administered separately in the same ratio (see page 6, lines 17-20; addresses applicant's claims 14, 17, 20, 25, 26, and 28). Non-toxic and chemically inert diluents, additives, and carriers are used in the composition, such as lactose (see page 7, lines 1-3; addresses applicant's claim 23 and 24). The amounts of active agents per dose of inhalation are disclosed on pages 7-9, which calculate up to 8 inhalation per day without going over the maximum daily dosage. For administration, the combination is suitably

inhaled from a nebulizer, from a pressurized metered dose inhaler or as a dry powder from a dry powder inhaler (see page 6, last paragraph, addresses claims 43 and 44). The micronized mixture may be suspended in a liquid propellant mixture. The propellants may be chlorofluorocarbons of different chemical formulae. The most frequently used chlorofluorocarbon propellants include tetrafluoroethane (P134a) and 1,1-difluoroethane (P152a; see page 7, lines 15-25; addresses claims 45-47).

Carling et al. does not specifically teach one or more additional doses on an irregular, as-needed basis for rescue purposes, as determined by the patient (claim 13), based on the patient's symptoms, when (1) the patient experiences an increase in asthma symptoms as set forth in applicant's claim 13; or (2) when the patient is expecting to encounter an asthma inducing condition, wherein the inducing condition is selected from the group consisting of exposure to cold air, exposure to pollen, exposure to perfume, exercise, or exposure to a smoky environment (applicant's claims 34, 36, 50 and 51). Carling et al. does not teach to inhale additional doses as needed to improve control and provide acute relief (applicant's claim 42). Carling et. al. also does not teach the particle size of the active ingredients (applicant's claim 22), or the specific propellant P227 (claim 47).

To one of ordinary skill in the art, it would have been obvious to combine the method of Carling et al. and administering the method on an irregular, as-needed basis

for rescue purposes, as determined by the patient in any of the circumstances detailed in claims 13, 34, 36, 42 and 49-50 because Carling et al. teaches that the dosages strongly depends on the severity of disease, whether mild, moderate, or sever asthma (see pg 6, lines 27-29), and the suitable daily dosage is up to 8 inhalation (see page 7-9).

The motivation to combine the methods and compositions of Carling et al. and instructing the patient to inhale, on demand in any of the circumstances detailed in claims 13, 34, 36, 42 and 49-50 because Carling et al. teaches that the dosages strongly depends on the severity of disease and to achieve maximum benefit of daily dosage recommended. It is noted by Carling et al. that the combination of formoterol with budesonide is well known to be beneficial for the treatment of asthma (see page 4, lines 4-21). Moreover, if the patient is experiencing acute asthmatic attack even with ongoing twice a day dosing regimen, the patient can still safely inhale an additional 6 inhalations without going over the maximum suitable daily dosage. In general, Carling et al. teaches therapeutic relief from asthmatic attack. The skilled artisan would have been motivated to instruct the patient to use the Carling et al. composition as needed on the bases of up to 8 inhalations a day is for reasonable expectation of successfully achieving maximum benefit in the treatment of any level of the asthma condition, including an increase in asthma symptoms, acute asthmatic condition, maintenance treatment, and common asthma triggers. Additionally, due to the urgency of therapy during an asthma attack, a patient would obviously seek relief with the medication

without consulting with the physician, in knowing the safe daily dosage range of each medication.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Carling et al. and the particle size of active agents set forth in claim 22, because they are known by a skilled pharmacologist and represent conventional formulations.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Carling et al. and the specific propellant P227 because Carling et al. teach that the propellants may be chlorofluorocarbons of different chemical formulae. Carling et al. also teaches some of the most frequently used, such as Applicant's claimed tetrafluoroethane (P134a) and 1,1-difluoroethane (P152a; see page 7, lines 15-25; addresses claims 45-47).

Claim 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record as applied to claims 13-15, 17, 18, and 20-29, 34, 36, 42-50, and 52-55 above, in view of Aberg et al. and in further view of Ryrfeldt et al.

Carling et al. teaching are as applied to claims 13-15, 17, 18, and 20-29, 34, 36, 42-50 and 52-55 above.

Carling et al. does teach the (R,R) enantiomer of formoterol set forth in claim 16 and the 22R epimer of budesonide set forth in claim 19.

Aberg et al. teaches (R, R) isomer of formoterol as required by claim 16 is a potent bronchodilator with reduced adverse effects in treatment of asthma. (abstract, column, 1, lines 25-35).

Ryrfeldt et al. teaches that the 22R epimer of budesonide is more potent in the treatment of bronchial asthma than 22S epimer (see page 17, column 1, paragraph 2, lines 12-15).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Carling et al. and the (R,R) enantiomer of formoterol and the 22R epimer of budesonide because Aberg et al. and Ryrfeldt et al. teach that these specific isomers possess potent asthmatic effect.

The motivation employ the (R,R) isomer of formoterol and 22R epimer of budesonide in the Carling et al. composition is because there is a reasonable expectation of successfully treating asthmatic patients with a more effective medication with reduced adverse effects.

Claim 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record as applied to claims 13-15, 17, 18, and 20-29, 34, 36, 42-50, and 52-55 above, in view of Trofast.

Carling et al. teaching are as applied to claims 13-15, 17, 18, and 20-29, 34, 36, 42-50 and 52-55 above.

Carling et al. does teach the specific amount of 4.5 μg of formoterol fumarate dihydrate or the specific amounts of budesonide in claims 57-66.

Trofast teach that formoterol fumarate dihydrate can be administered via inhalation from 3 to 24 μg in doses of 3, 4.5, 6, 9 or 12 μg (see column 12, lines 2-6).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Carling et al. and the specific amounts of formoterol fumarate dehydrate and budesonide to a patient because of the following teachings: 1) Clarling et al. teach that Formoterol (formoterol fumarate dehydrate) is administered in a suitable daily dose in a range of 6 to 100 μg with a daily dose of budesonide in a range of 50 to 4800 μg (see page 6, lines 24 and 26); 2) Trofast teach that formoterol fumarate dihydrate can be administered via inhalation from 3 to 24 μg in doses of 3, 4.5, 6, 9 or 12 μg (see column 12, lines 2-6); 3) A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed

in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974); and 4) it is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

(10) Response to Argument

The Appellants argue that the examiner must consider the claimed invention as a whole and must view the reference without the benefit of impermissible hindsight vision. The art understood that inhaled steroids do not give immediate symptom relief and do not relieve an acute asthma attack. This is an important point, because the rejection appears to be based on an unstated assumption that one of ordinary skill in the art at the time of the invention would have believed it obvious to utilize a composition containing budesonide to relieve the immediate symptoms of asthma. Allowing the patient to take additional doses of a combination budesonide/formoterol composition, and leaving it to the patient's discretion to decide when and how many of those additional doses to take according to the patient's determination of need, would greatly reduce the number of severe asthma attacks suffered by the patient; and that this could be done without incurring in practice a substantial risk of overdose of budesonide. The Carling reference does not teach administration "on demand" or "as needed". The Examiner's response to the why one would

> take more than the recommended doses is based on assumptions. The physician will determine the fixed dose not the patient and that the dose is not dependent on the number of puffs. There is no evidence of record to support the Examiner's position whereas the Appellants have provided several exhibits to support their argument. First, once one understands how inhaled glucorticosteroids such as budesonide were typically prescribed for asthma patients prior to Appellant's invention, it is apparent that Appellant's interpretation of Carling et al. is the one that a person of ordinary skill would have taken from this reference. Specifically Exhibits 1-3 demonstrate this evidence.

The Examiner continues to disagree for the same reasons given before and repeated below with some further explanation. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Examiner would like to start with the emphasis on breadth of the claims. First, the claim 13 reads on a method of treating asthma comprising administering a composition comprising an admixture of formoterol and budesonide. The method steps comprise administering the above composition in a maintenance dose twice per day on a regular basis and one or more additional doses on an irregular basis as-needed as determined by the patient. The claim limitation "as-needed" reads on zero to as many as the patient needs to administer the composition to treat asthma. Therefore, the claim reads on a minimum of the patient taking the

maintenance dose and not taking any more doses because it was not needed. With the limitation "as needed" addressed, Carling et al. obviously teaches claim 13. In regards to the additional doses if the patient needs it, one would be find it obvious and motivated that a patient could take an additional dose because Carling et al. teaches that the dosages strongly depends on the severity of disease, whether mild, moderate, or sever asthma (see pg 6, lines 27-29), and the suitable daily dosage is up to 8 inhalation (see page 7-9). The motivation to combine the methods and compositions of Carling et al. and instructing the patient to inhale, on demand in any of the circumstances detailed in claims 13, 34, 36 and 42 because Carling et al. teaches that the dosages strongly depends on the severity of disease and to achieve maximum benefit of daily dosage recommended. It is noted by Carling et al. that the combination of formoterol with budesonide is well known to be beneficial for the treatment of asthma (see page 4, lines 4-21). Moreover, if the patient is experiencing acute asthmatic attack even with ongoing twice a day dosing regimen, the patient can still safely inhale an additional 6 inhalations without going over the maximum suitable daily dosage. In general, Carling et al. teaches therapeutic relief from asthmatic attack. The skilled artisan would have been motivated to instruct the patient to use the Carling et al. composition as needed on the bases of up to 8 inhalations a day is for reasonable expectation of successfully achieving maximum benefit in the treatment of any level of the asthma condition, including an increase in asthma symptoms, acute asthmatic condition, maintenance treatment, and common asthma triggers. Additionally, due to the urgency of therapy during an asthma attack, a patient would obviously seek relief with the medication

without consulting with the physician, in knowing the safe daily dosage range of each medication.

> Exhibit 1 is a potent teaching-away from the present claimed invention, but the Examiner continues to ignore it because it is not a "true comparison".

The Examiner maintains the previous arguments and repeats that the evidence provided in Exhibit 1 is not a true comparison of the claimed invention because the Exhibit 1 is administration of budesonide as the sole active ingredient, while the claimed invention is an admixture of budesonide and formoterol. Although the Applicant's argue that the evidence is a teaching away and not a showing of unexpected results, a true comparison cannot be made between the sole product and a combination. The Examiner has provided art of the Applicant's claimed combination through Carling et al. Carling et al. teaches that the combination of the two drugs have greater efficiency and duration of bronchodilator action, and rapid onset action, which provides rescue medicine, adequate dosing for treating asthma (see page 4, lines 4-21). Regardless of if it is provided "as needed" or "twice a day", it is the combination of the specific drugs that provide the above benefits. Thus, the specific combination is different from either compound alone. In order to truly compare the two compositions both compounds need to be present.

> Similarly, Exhibits 2 and 3 are product inserts instructing a set dose, twice per day even though the products were published years after the present applications' priority date. In response to

> Examiner's response to the statements D and E of Exhibit 2, U.S. law does not require Appellant to show that something is "impossible" in order to prove that it is not obvious. Nor is the proper question whether some patient somewhere might ignore instructions regarding proper use of the Symbicort product for maintenance treatment in accordance with the Exhibit 2 product insert, and accidently or intentionally take a larger dose than his/her physician prescribed. Further, it is unclear why the Examiner believes that the statements in sections D and E of Exhibit 2 "verifies the Examiner's statement that patients will take more than the current dose if needed" and "obviously address the patients that use the medication 'as needed' even though is not recommended." The Appellants do not support these assertions. Section D clearly communicates that exceeding the current dose is potentially dangerous and is not to be done under any circumstances. Section E says that increasing use of the short-acting beta2 agonists, not Symbicort, indicates that the patient's overall asthma symptoms are worsening and in turn the Symbicort is not working and should be reassessed by the physician.

In regards to Exhibit 2, the Examiner continues to view statements D and E as verification that patients will take more than the current dose if needed. Although the additional doses are not recommended, the patient still chose to take an additional administration because the patient *feels the need* (i.e. as-needed) for treatment. In an asthma attack, if a patient is faced with not breathing and taking an additional administration within the safe inhalation amounts, one would find that the patient would take an as-needed administration. To clarify further, the insert obviously addresses the patients that use of the medication "as needed", thus proving that patients will use the medication "as needed" even though it is not recommended. In other words, the statements in D and E show evidence that patients will take additional medication when needed without the doctor's advice. Further, if the patient did not need the additional administration, the prior art clearly reads on the claimed invention. As discussed

before, regardless if the patient takes the additional dose, Carling et al. obviously reads on the claim for the reasons discussed above.

> The Examiner continues to dismiss the evidence in Exhibit 3 because it concerns compounds other than budesonide and formoterol. Exhibit 3 is not being cited as unexpected results thus it need not truly compare. Exhibit 3 provides that even after years after the present application, glucocorticosteroid-containing compositions in general should not be administered "as needed" or to relieve an acute asthma attack.

In regards to Exhibit 3, the admixture is of fluticasone and sameterol, which are two drugs not even claimed in the current application. The Examiner acknowledges what the Appellant is trying to convey but the Examiner still finds the administration "as needed" obvious for reasons above. Additionally, the Examiner continues to makes the point that Carling et al. teaches that the combination of the two drugs claimed have greater efficiency and duration of bronchodilator action, and rapid onset action, which provides rescue medicine, adequate dosing for treating asthma (see page 4, lines 4-21). Thus, the specific combination is different from either compound alone. Different compounds have different properties and as evidenced by Carling et al. the combination of two known compounds can also possess different properties and characteristics. In order to truly compare the two compositions of Exhibit 3 and the claimed combination both compounds need to be present.

> Exhibits 5 and 6 provide teaching that the current invention is not obvious. Barnes and D'Urzo viewed use of a budesonide/formoterol combination in accordance with the present

> claims to not have been "obvious" in view of standard asthma therapy, i.e. therapy in which a glucocorticosteroid is used solely for maintenance treatment, never as-needed as a reliever. The Examiner does not explain why this evidence is not believable or does not overcome the rejections but repeats the arguments to Exhibit 2.

The Examiner has considered the comments made by Barnes, O'Byrne et al. and D'Urzo, but does not find that the evidence overcomes the prior art for the reasons stated above and below. The reasons for the evidence not overcoming the rejections are repeated below. Carling et al. teaches that the combination of budesonide and formoterol have greater efficiency and duration of bronchodilator action, and rapid onset action, which provides rescue medicine, adequate dosing for treating asthma (see page 4, lines 4-21), thus the Applicant's results are not viewed as surprising. The combination of Carling et al. provides suitable daily doses for asthma, but does not completely eliminate a patient taking more than two administrations a day. Suitable daily treatment is dependent on the patient's severity of the condition, weight, height, and age. Again, just because the combination is recommended to be taken twice daily does not mean that changes could not be made to accommodate the patient to treat asthma (i.e. successful result). Thus, the prior art reads on the patient taking an additional as-needed administration of the combination treatment, and as discussed above even if no additional dose was needed Carling et al. still reads on the claims.

> The Appellant argues that even if Carling et al. teaches that particular dose depends strongly on patient specific factors, they do

> not provide any motivation to discard what was widely known about glucocorticosteroid treatment and instead give the patient free rein to inhale additional doses of the composition as needed, as determined by the patient. The Examiner's view that "due to the urgency of therapy during an asthma attack, a patient would obviously seek relief with the medication without consulting with the physician…", reflects a misunderstanding of the nature of the medication. Short-acting bronchodilators were given for emergency inhalers never a steroid or a combination containing a steroid.

The Examiner maintains the response to the specific factors as stated above and by the Appellant influencing the particular dose of the combination. Further, Exhibit 2, statements D and E, verifies that patients will take more than the current dose of the combination therapy if needed. Although the additional doses are not recommended, the patient still chose to take an additional administration because the patient *feels the need* (i.e. as-needed) for treatment. In an asthma attack, if a patient is faced with not breathing and taking an additional administration within the safe inhalation amounts, one would find that the patient would take an as-needed administration.

> In response to Examiner's response regarding "expectation of success", the Appellant has provided ample additional evidence that one skilled in the art in 1998 (Exhibit 1) and 2001 (Exhibit 2) would not have reasonable expectation of success under the scenario the Examiner believes is obvious. Additionally, the Appellant has provided surprising results as taught by O'Bryne in Exhibit 5. In response to Examiner's response to the surprising results, even though the budesonide/formoterol combination had advantages according to Carling et al., further advantages could not have been seen by adding additional inhalations as needed. Further, Kuna et al. (Exhibit 7), Rabe et al. (Exhibit 8), Scicchitano et al. (Exhibit 9) and Bousquet et al. (Exhibit 10) further evidence of surprising results. The Examiner does not dispute in Kuna et al. the present claims achieved surprising results but focuses on that all treatments were equivalent and that asthma is still treated. The

> Appellant is not alleging that the Carling et al. method provides no benefit in treating asthma, however it is surprisingly better. Further, the Exhibits such as Barnes, Scicchitano et al. and D'Urzo discloses that there is a long felt, unsatisfied need for an effective asthma treatment.

The Examiner continues to find that Kuna et al. is not persuasive to overcome the art because Kuna et al. also teaches that all treatments provided similar marked improvements in lung function, asthma control days and asthma-related quality of life (see abstract). Additionally, Kuna et al. also teaches that all treatments were well tolerated (see abstract). Scicchitano et al. teach a comparison between budesonide/formoterol for both maintenance and symptom relief versus a higher maintenance dose of budesonide. Bousquet et al. teach a comparison between the claimed invention and a combination of salmeterol/fluticasone, in which the claimed invention reduced exacerbations. Although, the adjustable maintenance dosing is more effective, Scicchitano et al. also teaches that both the fixed and adjustable dosing treatments were equally well tolerated (see page 1404, right column, last six lines). The Examiner would still like to point out that the Carling et al. method still effectively treats asthma, and discloses that the combination provides better results than the individual medications alone. In regards to the additional "as-needed" dose, the Examiner has addressed this limitation in depth above and sill maintains this view. Thus, Carling et al. obviously teaches the claimed invention.

> The Appellant states that the Examiner stated on page 10 and page 11 of the Final Office Action that Carling et al. does teach either the isomer of formoterol set forth in claim 16 or the specific amounts disclosed in claims 57-68. The Appellant assumes that the statement was made in error and should be that Carling et al. does not teach the isomer of formoterol set forth in claim 16 or the amounts in claims 57-68. Besides the above, Aberg et al., Ryrfeldt et. al., or Trofast does not make up for Carling et al.'s deficiencies.

The Examiner agrees that the omission of "not" was a clerical error and should be included.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section were provided by the Appellant in the Appendix (x).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/KENDRA D CARTER/

Examiner, Art Unit 1627

Conferees:

/Jon D. Epperson/

Primary Examiner

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627